

Group IV: Claims 18-20, drawn to an antibody specific to MOAT-C.

Group V: Claims 21 and 59, drawn to an oligonucleotide which specifically hybridizes with a protein translation initiation site in a nucleotide sequence encoding SEQ ID NO: 4 and a kit containing oligonucleotide primer sequences for amplification.

Group VI: Claims 22 and 59, drawn to an oligonucleotide which specifically hybridizes with a protein translation initiation site in a nucleotide sequence encoding SEQ ID NO: 2 and a kit containing oligonucleotide primer sequences for amplification.

Group VII: Claim 23-29, 45-51 and 56-58, drawn to an isolated nucleic acid molecule having the sequence of SEQ ID NO: 5 (MOAT-D), a vector comprising said nucleic acid molecule, a host cell containing said nucleic acid molecule, and a method for screening a test compound for inhibition of MOAT mediated transport using said host cell.

Group VIII: Claims 30-32, drawn to an antibody specific to MOAT-D.

Group IX: Claims 33 and 59, drawn to an oligonucleotide which specifically hybridizes with a protein translation initiation site in a nucleotide sequence encoding SEQ ID NO: 6 and a kit containing oligonucleotide primer sequences for amplification.

Group X: Claims 34-40, 45-51 and 56-58, drawn to an isolated nucleic acid molecule having the sequence of SEQ ID NO: 7 (MOAT-E), a vector comprising said nucleic

acid molecule, a host cell containing said nucleic acid molecule, and a method for screening a test compound for inhibition of MOAT mediated transport using said host cell.

Group XI: Claims 41-43, drawn to an antibody specific to MOAT-E.

Group XII: Claims 44 and 59, drawn to an oligonucleotide which specifically hybridizes with a protein translation initiation site in a nucleotide sequence encoding SEQ ID NO: 8 and a kit containing oligonucleotide primer sequences for amplification.

Group XIII: Claim 52-55, drawn to a transgenic animal comprising a nucleic acid molecule of SEQ ID NO: 1 or a homozygous null mutation in its endogenous MOAT-B gene.

Group XIV: Claim 52-55, drawn to a transgenic animal comprising a nucleic acid molecule of SEQ ID NO: 3 or a homozygous null mutation in its endogenous MOAT-C gene.

Group XV: Claim 52-55, drawn to a transgenic animal comprising a nucleic acid molecule of SEQ ID NO: 5 or a homozygous null mutation in its endogenous MOAT-D gene.

Group XVI: Claim 52-55, drawn to a transgenic animal comprising a nucleic acid molecule of SEQ ID NO: 7 or a homozygous null mutation in its endogenous MOAT-E gene.

Applicants respectfully submit that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in §1893.03(d) of the M.P.E.P.:

Examiners are reminded that unity of invention (**not restriction**) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P. (Emphasis added.)

It is noteworthy that, during the international stage of this application, no lack of unity was identified by the Examiner in the Written Opinion issued April 13, 2000.

Plainly, the restriction requirement of December 12, 2002 fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. Accordingly, Applicants respectfully request the restriction requirement be withdrawn.

Additionally, Applicants strongly disagree with the Examiner's assessment that groups I, III, VII and X do not relate to a single general inventive concept under PCT Rule 13.1. Applicants contend the nucleic acid molecules encoding for the various MOAT proteins share sufficient commonalities to meet the requirement of unity of invention set forth in PCT Rule 13.1. Specifically, encoded for MOAT-B, MOAT-C, MOAT-D, and MOAT-E are all classified within the same MRP/cMOAT-related family of transporters. As noted in claims 1, 11, 23 and 34 of groups I, III, VII and X, respectively, all of the MOAT transporter proteins consist of a tandem repeat domain of nucleotide binding folds containing Walker A and B binding sites and a C-terminal hydrophobic domain having a plurality of membrane spanning helices. Moreover, the amino acid sequences of the MOAT proteins exhibit at least 30% identity with one another. In summary, the restriction requirement is inappropriate and should be withdrawn because the claimed inventions share special technical features and form a single general inventive concept.

Applicants also contend the same arguments set forth above for the withdrawal of the restriction requirement among groups I, III, VII and X can be made with regards to the restriction of groups II, IV, VIII, and XI, groups V, VI, IX, and XII, and groups XIII-XVI. These groups differ only with regard to which MOAT protein the claims are drawn to. Therefore Applicants assert that the claimed inventions do, in

fact, share special technical features and form a single general inventive concept. In light of all of the foregoing remarks, Applicants request that the requirement for restriction be withdrawn or at the very least modified.

In order to be fully responsive to the restriction requirement identified hereinabove, Applicants hereby elect the subject matter of Group I for consideration in this application, namely claims 1-7, 45-51 and 56-58. These claims are drawn to an isolated nucleic acid molecule having the sequence of SEQ ID NO: 1 (MOAT-B), a vector comprising said nucleic acid molecule, a host cell containing said nucleic acid molecule, and a method for screening a test compound for inhibition of MOAT mediated transport using said host cell.

Applicant hereby reserves the right to file one or more continuation applications under 35 U.S.C. §120 on the subject matter of all claims ultimately withheld from consideration in the present application.

Early and favorable action on this application is earnestly solicited.

Respectfully submitted,  
DANN, DORFMAN, HERRELL AND SKILLMAN

By   
Kathleen D. Rigaut, Ph.D., J.D.  
Reg. No. 43,047

Telephone: 215-563-4100